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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,591	07/25/2003	Andrew Clark	0029.10	2973

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NEKTAR THERAPEUTICS
201 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER	
DOUGLAS, STEVEN O	
ART UNIT	**PAPER NUMBER**
3771	

MAIL DATE	DELIVERY MODE
12/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/627,591	CLARK ET AL.	
	Examiner	Art Unit	
	/Steven O. Douglas/	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-52* is/are pending in the application.

4a) Of the above claim(s) *25 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,24,26 and 28-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23,24,26, and 28-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Rubsamen et al. US 5,735,263.

Regarding claims 23, 29, 28, 31-36, and 38-40, Rubsamen discloses a device (see the device of figs.1 and 10) for increasing the bioavailability of an aerosolized active agent, said device comprising a flow restrictor (9,22,37). Rubsamen in column 5, lines 50-55, column 13, lines 5-10, 25-30, and 52-57, column 23, lines 34-55 discloses that a microprocessor controls and monitors the inspiratory flow of an aerosolized active agent formulation to a human patient (though the valve in the case of fig.1 and though the opening of the mouthpiece in the case of fig.10) at a rate of 0.1 to 2 liters per second ~ 6 to 12 liters per minute, which meets claimed flow rate of "less than 17 liters per minute" and "10 liters per minutes". Rubsamen further discloses wherein the device is adapted to aerosolize the active agent formulation and wherein the active agent formulation is (i) a powder, (ii) a solution, suspension, or slurry that may be nebulized, or (iii) suspended or dissolved in a propellant (see col.14, lines 64-67, and col.15, lines 1-6). Rubsamen further discloses the active agent formulation is a powder (see col.14, lines 64-67, and col.15, lines 1-6) and the device is adapted to aerosolize the active agent formulation (see col.29,

lines 26 and 27) using compressed air (see col.31, lines 15-20). Rubsamen further specifically discloses the device is adapted to be used with an active agent selected from the group consisting of insulin (see col.22, lines 49 and 50).

Regarding claim 26, Rubsamen discloses the flow restrictor is a valve (fig.1, 9) and microprocessor (22,27) controlling the inspiratory flow rate though the valve would provide for adjustment of the valve so that it decreasing resistance with increasing flow rate in order to provide an inspiratory flow rate of 6-12 liters per minutes.

Regarding claims 30,37, 41, 46, and 52, Rubsamen in figure 10 discloses the active agent formulation is contained in a blister (56) and the device is adapted to receive the blister.

Regarding claims 24, 42-45, Rubsamen discloses the claimed invention as applied for claims 23, 29, 28, 31-36, and 38-40. Notice, opening through the mouthpiece in figure 10 and flow passage blocked by the valve in figure 1 is considered orifice of claims 24 and 42.

Regarding claims 47 and 48, Rubsamen discloses a device (see fig.1 and 10) for delivering an aerosolized active agent to the lungs of a human patient, said device comprising a chamber (3,55) in flow communication with a mouthpiece (12,52), means for aerosolizing the active agent (actuator/switch (see col.17, lines 15-17) releasing active agent into a flow path (8/54) would allow aerosolization of the agent in the air contained into the flow path; and patient's inhalation force can further assist in aerosolization of the active agent), and means for limiting an inspiratory flow rate (9,22,37). Rubsamen discloses flow rate of less than 17 liters per minute and 10 liters per minute or less as applied for claim 23. Rubsamen further discloses whereby an aerosolized active agent formulation in the chamber may be delivered to the human patient, the active agent formulation being (i) powder, (ii) a solution suspension, or slurry than

may be nebulized, or (iii) suspended or dissolved in a propellant (see col.14, lines 64-67, and col.15, lines 1-6).

Regarding claim 49, Rubsamen discloses the device is adapted to deliver an aerosolized insulin formulation to the lungs Rubsamen further specifically discloses the device is adapted to be used with an active agent selected from the group consisting of insulin (see col.22, lines 49 and 50).

Regarding claim 49, Rubsamen discloses the device is adapted to deliver an aerosolized insulin formulation to the lungs (see col.22, lines 49 and 50).

Regarding claim 50, Rubsamen discloses the device further comprising means for aerosolizing the active agent (see compressed air in col.31, lines 15-20).

Regarding claim 51, Rubsamen discloses the active agent formulation is a powder (see col.14, lines 64-67, and col.15, lines 1-6) and the device is adapted to aerosolize the active agent formulation (see col.29, lines 26 and 27).

Response to Arguments

Applicant's arguments filed 2/13/08 have been fully considered but they are not persuasive. In regard to Applicant's repeated argument that the solenoid valve arrangement of Rubsamen fails to meet Applicant's claimed limitation of a flow restrictor to limit the flow of aerosolized active agent to rate less than 17 liters per minute, Examiner disagrees. As pointed out in the rejection, the Rubsamen operates at a flow rate well within the claimed range and that it is the operation of the Rubsamen solenoid valve restricts the flow rate within the claimed rate. Furthermore, giving the term "restriction" or "restrictor" its broadest most reasonable

interpretation, a conventional valve (i.e. a solenoid-type or not) includes at least one of an orifice, opening or passage that includes a designed flow rate that is further actuated (i.e. restricted) by the associated valve element.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Steven O. Douglas/ whose telephone number is (571) 272-4885. The examiner can normally be reached on Mon-Thurs 6:30-5:00.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven O. Douglas/
Primary Examiner
Art Unit 3771

SD
12/17/08